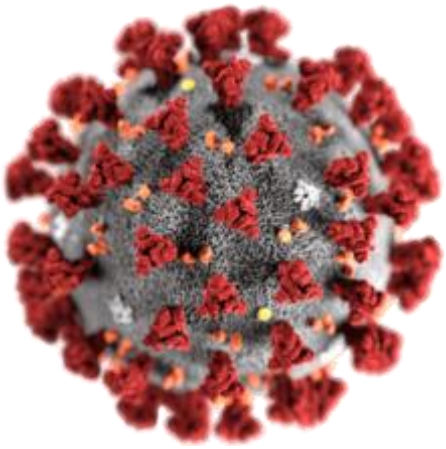
NUS National University of Singapore | Saw Swee Hock School of Public Health



COVID-19 Science Report: Diagnostics

NUS Saw Swee Hock School of Public Health
As of 12 Mar 2020

DOI: 10.25540/e3y2-aqye

Contents

Diagnostics

For regular readers of this report, the latest additions have been highlighted in blue.

Laboratory diagnosis plays an important role in disease and outbreak management. Fast and accurate laboratory diagnosis of a specific viral infection of interest contributes to prompt public health surveillance, prevention, and control measures. With wide accessibility and availability of an accurate laboratory diagnosis for early detection, local transmission and clusters can be prevented or at least delayed by isolating the laboratory-confirmed cases in a healthcare facility, and to have their close contacts quarantined and monitored at home. Furthermore, this facilitates the implementation of specific public health intervention such as the closure of specific high-risk facilities and areas associated with the laboratory-confirmed cases for prompt infection control and environmental decontamination.[1,2]

Current Diagnostics

Appendix A is a summary of the latest non-commercial laboratory diagnostic protocols listed on WHO's COVID-19 webpage, available or upcoming commercial and non-commercial diagnostics, and summary of approaches for laboratory diagnostics of coronaviruses by Zhang et al (2020).[3] Diagnostics that can be used for point-of-care testing have been noted in Table 2 in the first column.

Detection of Viral Genetic Material

Chinese health authorities have posted the full genome of SARS-CoV-2 in GenBank and GISAID portal.[1] Several lab assays have been developed to detect SARS-CoV-2, as highlighted in WHO's guidance to COVID-19 laboratory testing of suspected cases. WHO first published five protocols for diagnostics using reverse transcriptase polymerase chain reaction (RT-PCR) on their COVID-19 webpage. These included protocols from Charité Institute of Virology in Germany and The University of Hong Kong (HKU), as well as those from Thailand, Japan, and China. A sixth protocol from US Centers for Disease Control and Prevention (CDC) was subsequently added on WHO's webpage on 29 January 2020.[4] The WHO webpage has since been updated with a different URL and with additional guidance documents.[5] A seventh protocol from Institut Pasteur in Paris, France, was added on WHO's webpage in March 2020.[6]

It should be noted that the protocols for diagnostics using RT-PCR published on WHO's webpage is for guidance and not an exhaustive list. Various institutions and governments have chosen to develop their own protocols that might not be publicly available or published by WHO on their webpage.

As outlined in the sixth national treatment and diagnostic plan issued by China's National Health Commission, the diagnosis of COVID-19 still requires the detection of the genetic material of SARS-CoV-2 before classification as a confirmed case.[7]

The first validated diagnostic test was designed by Prof Christian Drosten's group from Charité Institute of Virology in Berlin, Germany.[1,8] The initial RT-PCR assay design was based on the SARS-CoV or SARS-related coronavirus, but with the release of the sequence, assays were selected based on the match against the Wuhan virus. Two assays were used for the RdRP gene and E gene where E gene assay acts as the first-line screening tool and RdRp gene assay as the confirmatory testing. All assays were highly sensitive and specific, and do not cross- react with other coronavirus and also human clinical samples that contain respiratory viruses.

HKU uses two monoplex assays reactive with coronavirus under the subgenus Sarbecovirus which consist of SARS-CoV-2, SARS-CoV, and SARS-like coronavirus.[9,10] Viral RNA extracted from SARS-CoV could be used as the positive control. The N gene RT-PCR could be used as a screening assay and Orf1b assay as a confirmatory test. However, this protocol has only been evaluated with a panel of controls and only positive control, SARS-CoV RNA. Synthetic oligonucleotide positive control or SARS-CoV-2 have yet to be tested. This protocol has since been published in Clinical Chemistry on 31 January 2020.[10]

US CDC has shared the protocol for rRT-PCR assay with the primers and probes designed for the universal detection of SARS-like coronavirus and the specific detection of SARS-CoV-2.[11,12] However, the protocol has not been validated in other platform or chemistries apart from the protocol described, and the analyst has to be trained and familiar with the testing procedure and result interpretation. As of 4 February 2020, US CDC has obtained emergency use assessment (EUA) from the US Food and Drug Administration (FDA).[13] This allowed US CDC to ship their diagnostic test kits to laboratories that are designated by CDC as qualified or certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high complexity tests in the US.

With the shipped US CDC diagnosis kits, however, quality control issues were found with reagents pertaining to the third step N3 gene assay for universal detection of SARS-like coronaviruses.[14] As such, US CDC is reportedly producing new test kits, and that those with existing kits were provided with new guidelines to continue without the third step N3 gene assay.[15,16] An investigation has also been launched, with major concerns raised in the preliminary stages.[17,18] The US Food and Drug Administration (FDA) has since announced on 29 February 2020 a change in policy for certain laboratories to develop and begin using validated COVID-19 diagnostics (other than the only EUA-approved US CDC) before the FDA has completed the EUA review.[17,19]

Currently, most of the available diagnostics have focused on packaging the appropriate reagents and genetic primers and probes for using RT-PCR to amplify genetic material for detection of SARS-CoV-2. Additional methods include using microarray or microfluidic lab-on-chip technologies, CRISPR to isolate gene segments for diagnostics, and full genetic sequencing. The use of microarray or microfluidic technologies for miniaturised fast detection of genetic material in some instances could be considered to be rapid point-of-care testing, as samples could be run on miniaturised and/or automation machinery instead of a full laboratory. However, the caveat would be that the accompanying machinery and reagents are widely distributed and available across different sites and/or in the field.

Serological Testing

For diagnosis of acute infections, there is a lag period as antibodies specifically targeting the virus would normally appear between 7-14 days after the illness onset. However, serological tests can be used to assess both active and historical infection within the community. Serological tests using immunoassay test strips can also provide rapid point-of-care qualitative detection of antibodies for better screening before further confirmatory tests.

Singapore has developed an approach of using serological testing to diagnose cases that earlier had COVID-19.[20,21] This test for the antibodies for SARS-CoV-2 was developed by Prof Wang Linfa's group in Duke-NUS Medical School.

Rapid IgM antibody test strips have been developed by Guangzhou Medical University under the guidance of famed researcher Dr Zhong Nanshan and are already in use in China.[7,22] Guangzhou Wondfo Biotech and Innovita Biological Technology have already received EUA approvals from the China National Medical Products Administration for their antibody test kits.[23-26] Guangzhou Wondfo Biotech has also obtained CE Mark for their Wondfo SARS-CoV-

2 Antibody Test (Lateral Flow Method) that tests for both IgM and IgG antibodies.[27,28] Pharmact AG from Germany,[29] Zhejiang Orient Gene Biotech,[30,31] and SD Biosensor[32] have commercially available immunoassay test strips for qualitative detection of antibodies that can be used for point-of-care testing. Other rapid test kit development and commercialisation efforts by Jiangsu Medomics Medical Technologies,[33] Shenzhen Tisenc Medical Devices,[34] and Nankai University[35] are also underway. These test strips are all expected to take about 15 to 20 minutes, a major time reduction compared to using RT-PCR.

Jiangsu Medomics Medical Technologies have created a point-of-care lateral flow immunoassay that simultaneously detects both IgM and IgG antibodies against SARS-CoV-2.[33] In a published Journal of Medical Virology paper by Li et al (2020), the team found a sensitivity of 88.66% and specificity of 90.63% through testing samples from 397 positive case patients and 128 negative control patients.[36] The use of whole blood (diluted with buffer to improve flow) can be used and can produce results within 15 minutes. Comparison of fingerstick whole blood with both plasma and serum from venous blood found no differences in results for 7 positive case patients and 3 negative control patients. By using both IgM and IgG, the test can be used for detection of patients at different infection stages.

Imaging

In the sixth national treatment and diagnostic plan issued by China's National Health Commission, cases diagnosed using chest CT Scans were not continued as part of the count of new confirmed cases.[7] China had previously announced that they would include in the count of COVID-19 cases, those that were diagnosed using chest CT Scans.[37] This was due to the limited diagnostic kits and resources for testing of SARS-CoV-2 genetic material. This proposed method of early diagnosis has been explored and published in the Radiology journal.[38,39] Some studies have indicated, albeit with small samples, that CT scans could show indications of COVID-19 before onset of symptoms or positive RT-PCR test.[40-42] Alibaba has also developed an artificial intelligence (AI) model using data from 5000 confirmed cases that has 96% accuracy rate in detecting differences in chest CT scans to distinguish patients with COVID-19 vs ordinary viral pneumonia.[43]

Issues with Diagnosis Approaches

Specimen Sample Collection

The sites of biological sampling can affect the sensitivity of diagnostic tests relying on detection of genetic material. A previous study by Kim et al (2011) has found that detection strengths of using nasopharyngeal (nasal) or oropharyngeal (throat) swabs differ for different pathogens infecting the respiratory tract, and that not one is superior than the other for all cases.[44]

For SARS-CoV and MERS-CoV, specimens collected from the lower respiratory tract such as sputum and tracheal aspirate have higher and more prolonged levels of viral RNA. MERS-CoV viral load is also higher for severe cases and has longer viral shedding as compared to the mild case. Although upper respiratory tract specimens such as nasal or throat swabs could be used, it has a lower viral load and could result in false-negative tests among the mild cases.[45,46] This is one key characteristic that may be similar to SARS-CoV-2.

Current recommendation by US CDC requires the use of BOTH nasal and throat swabs to obtain specimen from upper respiratory tract of potential case with COVID-19 for diagnostic testing using RT-PCR.[47] However, initial rapid guidelines from China only indicated the use of throat swabs.[48]

Latest published findings from Yang et al (2020) specific for COVID-19 have found that testing of specimens obtained from nasal swabs, as well as from sputum, are more effective than throat swabs, for the detection of SARS-CoV-2.[49] The authors warned that "throat swabs were not recommended for the viruses detection, especially the samples collected 8~14 and ≥15 days after onset of illness (d.a.o.) from mild cases, which may result in a large proportion of false negative results." The authors concluded that "sputum is most accurate for laboratory diagnosis of (COVID-19), followed by nasal swabs, while throat swabs was [sic] not recommended for the diagnosis." However, the authors recognised the limitation that preliminary investigations found that only about a quarter of COVID-19 patients showed had production.

Interestingly, the authors found that for severe cases, bronchoalveolar lavage fluid (BALF) had 100% positive detection rate while specimens from upper respiratory tract (sputum, nose swab, and throat swab) did not have as strong detection rates.[49] This might be a case whereby the severe cases reflect the deep infection of the lower respiratory tract, causing the pneumonia-like symptoms. The use of only nasal or throat swabs to get at an official diagnosis could thus prove to be frustrating, particularly when specimens from the upper respiratory tract might show a negative result even though all clinical signs indicate otherwise. This could cause delayed diagnosis, containment actions, and treatment regimes, and as such, the recommendation of CT scans as an added layer. On the contrary, the small sample of three patients that were mild cases with BALF tested had 0% positive detection. It could be these cases are mild because the SARS-CoV-2 did not infect the lower respiratory tract but remained in the upper respiratory tract, which allowed for better detection if using samples from sputum or nasal swabs.

A limitation of the Yang et al (2020) study was that it was conducted with COVID-19 patients that have already been admitted to the hospital and started on antiviral treatments.[49] Their findings might thus be limited in being fully applicable to the scenario of diagnosis of potential cases. However, the study does also raise questions on the risk of false negatives leading to early discharges out of isolation and quarantine of existing diagnosed cases.

To note, nasal and throat swabs:

- could cause discomfort and even bleeding
- would require experienced healthcare provider to administer
- could risk exposure to healthcare provider
- does not obtain specimens from lower respiratory tract

A study by To et al (2020) have found that SARS-CoV-2 was detected in saliva samples from 11 out of 12 COVID-19 patients.[50] This suggests that saliva samples could be a potential alternative or additional specimen for diagnostic testing, especially in scenarios with limited trained healthcare providers outside of the hospital setting, and with aim to reduce exposure risk during specimen collection.

Search Method

Searches have been conducted for the latest information related to diagnostics for COVID-19 (previously 2019-Novel Coronavirus or 2019-nCoV) since 28 January 2020. Searches were done on Pubmed and Google Search using key words that included: coronavirus; Wuhan; diagnostic; diagnostics; diagnosis; diagnoses; novel coronavirus; 2019 novel coronavirus; 2019-nCoV; COVID-19; SARS-CoV-2. Google Search results reviewed included webpages of: government and international bodies with official information and guidelines (WHO, Europe CDC, US CDC, US FDA), diagnostic protocols, scientific commentaries, market news, and press releases. All relevant links in the webpages were reviewed and relevant information

used and referenced. A latest list of potential commercial kits in the works was also provided on 29 January 2020 by Dr Kim J Png through personal communications. This list was compiled by Dr Png from web searches and review of latest business news. The list served to verify and supplement our team's own search above for review. Subsequently, a list of biomedical news sites (Bioworld, Genetic Engineering & Biotechnology News, GenomeWeb/360Dx, Verdict Medical Devices) were also reviewed regularly as "go-to" sites to provide latest updates on commercial diagnostics developments. To note, the latest information of diagnostics being used and developed in China remain scarce or difficult to review (in Chinese, not indexed in non-Chinese search engines, or not reported in non-Chinese media news outlets). Therefore, China news sources in English language (CGTN, ChinaDaily, Global Times) were used.

Appendix A

Table 1. Non-Commercial Laboratory Protocols

Type	Organisation	Date	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
rRT-PCR	**Charité Institute of Virology**, Berlin, Germany [1,51]	13 Jan 2020	**Primer and Probe** First line screening assay: E gene assay Confirmatory assay: RdRp gene assay Additional confirmatory assay: N gene assay	First line screening assay **Technical LOD:** 5.2 RNA copies/reaction, at 95% hit rate **95% CI:** 3.7-9.6 RNA copies/reaction. Confirmatory assay **Technical LOD:** 3.8 RNA copies/reaction, at 95% hit rate **95% CI:** 2.7-7.6 RNA copies/reaction. Additional confirmatory assay **Technical LOD:** 8.3 RNA copies/reaction, at 95% hit rate; **95% CI:** 6.1-16.3 RNA copies/reaction.	Chemical stability No positive signal detected for non-specific reactivity of oligonucleotides. Cross-reactivity with other coronaviruses No reactivity with any of three assays for five coronaviruses: (HCoV) -229E, -NL63, -OC43, -HKU1, and MERS-CoV Tests of human clinical samples previously tested to contain respiratory viruses All tests returned negative results for all 75 samples.	Available • SARS-CoV genomic RNA as positive control.	47 min 15 sec of cycle time (plus probe) for each assay	(no info)
rRT-PCR	**Charité Institute of Virology**, Berlin, Germany [1,8]	17 Jan 2020	**Primer and Probe** First line screening assay: E gene assay Confirmatory assay: RdRp gene assay	First line screening assay **Technical LOD:** 5.2 RNA copies/reaction, at 95% hit rate **95% CI:** 3.7-9.6 RNA copies/reaction. Confirmatory assay **Technical LOD:** 3.8 RNA copies/reaction, at 95% hit rate **95% CI:** 2.7-7.6 RNA copies/reaction. (Preliminary experiment compared single probe assay for SARS-CoV with single probe assay for SARS-CoV-2.)	Chemical stability No positive signal detected for non-specific reactivity of oligonucleotides. Cross-reactivity with other coronaviruses No reactivity with any of three assays for five coronaviruses: (HCoV) -229E, -NL63, -OC43, -HKU1, and MERS-CoV Tests of human clinical samples previously tested to contain respiratory viruses All tests returned negative results for all 75 samples.	Available • SARS-CoV genomic RNA as positive control. • Synthetic control RNA for SARS-CoV-2 E gene assay is available via EVAg. • Synthetic control for SARS-CoV-2 RdRp is expected to be available via EVAg from Jan 21st onward.	47 min 15 sec of cycle time (plus probe) for each assay	(no info)
rRT-PCR	**School of Public Health, The University of Hong Kong** (HKU)[9,10]	16 Jan 2020	**Primer and Probe** Assay 1 (Target: ORF1b-nsp14 gene)	Positive control using SARS-CoV RNA Wide dynamic range of 2^{-4} to 2000 $TCID_{50}$/reaction.	Exclusivity Negative results against all of these preparations: • RNA extracted from cultured viruses	Available • Positive control (Available from HKU) Primers and probes: • HKU-ORF1b-nsp14F	28 min 40 sec of cycle time for each assay	(no info)

Type	Organisation	Date	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			Assay 2 (Target: N gene)		• RNA from retrospective human clinical specimens previously tested positive for other infections • RNA from control human clinical specimens	• HKU- ORF1b-nsp14R • HKU-ORF1b-nsp141P • HKU-NF • HKU-NR • HKU-NP		
rRT-PCR	**Chinese Center for Disease Control and Prevention**, Beijing, China[52]	21 Jan 2020	**Primer and Probe** Target 1 (ORF1ab gene) Target 2 (N gene)	(no info)	(no info)	Available	(no info)	(no info)
RT-PCR	**Department of Medical Sciences, Ministry of Public Health**, Thailand[53]	Jan 2020	**With gel electrophoresis**	(no info)	(no info)	Available Primers: • NbatCoV_F1 • NbatCoV_R1	107 min of cycle time	(no info)
RT-PCR	**National Institute of Infectious Diseases**, Japan[54]	23 Jan 2020	**With gel electrophoresis** (Nested RT-PCR) **Primer and Probe** (Real-time RT-PCR)	(no info)	(no info)	Available Primers and probes: • NIID_2019-nCOV_N_F2 • NIID_2019-nCOV_N_R2 • NIID_2019-nCOV_N_P2	81 min for Nested RT-PCR 95 min for Real-time RT-PCR	(no info)
rRT-PCR	**Centers for Disease Control and Prevention**, Atlanta, USA[11,12]	24 Jan 2020	**Primer and Probe** 3 N gene targets 1 human RNase P gene control	(no info)	(no info)	Available Primers and probes: • 2019-nCOV_N1_F • 2019-nCOV_N1_R • 2019-nCOV_N1_P • 2019-nCOV_N2_F • 2019-nCOV_N2_R • 2019-nCOV_N2_P • 2019-nCOV_N3_F • 2019-nCOV_N3_R • 2019-nCOV_N3_P • RP_F • RP_R • RP_P	43 min 45 sec of cycle time for each assay	(no info)
rRT-PCR	**Institut Pasteur**, Paris, France[6]	2 Mar 2020	**Primer and Probe** 2 RdRp gene targets with	100 or more copies of RNA genome equivalent per reaction always detected.	Cross-reactivity with other respiratory viruses was tested and were all negative in reactivity with the two RdRp gene targets.	Available Primers and probes: • nCoV_IP2-12669Fw • nCoV_IP2-12759Rv	61 min of cycle time for each assay	(no info)

Type	Organisation	Date	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			Charité's E gene target as confirmatory	Samples containing 10 copies of RNA genome could be detected with multiplex assay.		• nCoV_IP2-12696bProbe(+) • nCoV_IP4-14059Fw • nCoV_IP4-14146Rv • nCoV_IP4-14084Probe(+) • E_Sarbeco_F1 • E_Sarbeco_R2 • E_Sarbeco_P1		

RT-PCR: reverse transcription polymerase chain reaction
rRT-PCR: real-time reverse transcription polymerase chain reaction
LOD: limit of detection
ORF: open reading frame
E gene: envelope gene
RdRp: RNA-dependent RNA polymerase
N gene: nucleocapsid protein gene
RNase P gene: Ribonuclease P gene

Table 2. Upcoming/Available Diagnostics

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
RT-PCR	Genesig[55,56] UK	Jan 2020	**Real-Time PCR COVID-19 (CE)** *[Previously Coronavirus (Strain 2019-nCoV) Easy/Standard Kit]*	(no info)	(no info)	Commercially available. Received CE Mark for IVD.	(no info)	(by quote)
RT-PCR	Bioperfectus Technologies[57] China	14 Jan 2020	**RT-PCR test kit**	(no info)	(no info)	Available as scientific research product – does not require registration[57]	(no info)	(no info)
Genome sequencing	Oxford Nanopore[58,59] UK	22 Jan 2020	Works with public health labs globally to support rapid sequencing of SARS-CoV-2 through sharing of methods / workflows. Nanopore sequencing workflows can provide a consensus viral genome from sample within a day.	(no info)	(no info)	Available.	(no info)	(no info)
End-to-end solution of sample processing to epidemiological info generation	Oxford Nanopore[58,60] UK	22 Jan 2020	**ARTIC project** A 'lab-in-a-suitcase' solution for processing samples from viral outbreaks, to generating real-time epidemiological information interpretable and actionable by public health bodies. Deployable to remote/resource-limited locations. Based on viral genome data generated prospectively during similar outbreaks (eg. MERS, SARS etc). Relies on direct amplification of the virus using tiled, multiplexed primers.	Not stated but described to have high sensitivity compared to metagenomic approaches.[61]	(no info)	(no info)	(no info)	(no info)
RT-PCR	Co-Diagnostics[62,63] USA	23 Jan 2020	**Logix Smart Coronavirus COVID-19 test**	Stated to be high but with no accompanying statistics.	No specific statistics but claims to have ability to reliably and accurately	Commercially available for sale on 10 Feb 2020.[63]	(no info)	(no info)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			RT-PCR kit with lower false positive		differentiate between similar genetic sequences, in order to reduce the likelihood of a false-positive diagnosis. Company shared that it achieves this by creating reactions that are far more specific than competing PCR technologies and 2.5 million times more effective in reducing amplification errors.[62,64]	Received CE Mark 24 Feb 2020.[65]		
RT-PCR	altona Diagnostics[66] Germany	23 Jan 2020	**Commercial Kit** RT-PCR kit	(no info)	(no info)	(no info)	(no info)	(no info)
RT-PCR	BGI[67] Pathomics Health (distributor) China	23 Jan 2020	**Fluorescent RT-PCR kit** In vitro RT-PCR combining fluorescent probing.[68]	(no info)	(no info)	Available. Received CE Mark for IVD 28 Feb 2020.[69] Currently used in hospitals and local disease control centres in China. BGI is also engaged with relevant organizations in Hong Kong, Taiwan, Brunei, Thailand, Nigeria, South Africa, to supply the test kits.[67] Passed emergency approval procedure of the National Medical Products Administration.	No data stated but described as 'can issue results in a few hours'.	(no info)
Combination of RT-PCR and meta-	BGI[67] Pathomics Health (distributor)[70]	23 Jan 2020	**2019-nCoV PMseq Kit** A metagenomics sequencing kit based on	(no info)	(no info)	Has been providing technical support for the scientific clinical prevention and	SARS-CoV-2 detection stated to be faster than	(no info)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
genomics detection	China		combinatorial Probe Anchor Sythesis. Faster SARS-CoV-2 virus detection, and able to detect both known and novel microorganisms, enabling monitoring of evolution during transmission.			control of the epidemic in Wuhan. Passed emergency approval procedure of the National Medical Products Administration.	Fluorescent RT-PCR kit. For detection of unknown pathogens, Within 5 hours, 128 samples can be simultaneously screened and sequenced by SE50, and 128 samples can be simultaneously tested and sequenced by PE100 in 22 hours, as well as possible mutation and evolution monitoring	
Microfluidic	Veredus Laboratories[71-73] Singapore	24 Jan 2020	**VereCoV** Lab-on-Chip platform integrating PCR and microarray Claims to detect MERS-CoV, SARS-CoV and SARS-CoV-2 in a single test	Stated to be high but with no accompanying statistics.[74]	Stated to be high but with no accompanying statistics.[74]	Available for RUO since Jan 2020. Provisional approval for IVD by Singapore's Health Sciences Authority since Mar 2020.[73] Used for testing of swab samples from Singapore's land, sea and air checkpoints since Mar 2020.[75]	2 hours[76]	(no info)
CRISPR-based diagnostics	Sherlock Biosciences[77-80] (Plus collaboration with Cepheid)[80] USA	24 Jan 2020	**SHERLOCK (Specific High-sensitivity Enzymatic Reporter unLOCKing)** SHERLOCK platform uses various CRISPR proteins (Cas13, Cas12a, and Csm6) to allow for simultaneous detection of multiple nucleic acids.[80]	(no info)	(no info)	Protocol published 14 Feb 2020.[81,82]	(no info)	(no info)
Microfluidic	Lexagene[83] USA	27 Jan 2020	Genetic analyser using microfluidic technology	(no info)	(no info)	Expected to be commercially available in Q3 2020.	1 hour	(no info)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
Real-time RT-PCR	Liferiver Biotech[84,85] China	29 Jan 2020	**Fluorescent PCR**[85]	(no info)	(no info)	Commercially available.	(no info)	€ 991[86]
Real-time RT-PCR	Liferiver Biotech[84,87] China	29 Jan 2020	**Multiplex RT-PCR**[87]	(no info)	(no info)	Commercially available.	(no info)	€ 1347[88]
Real-time RT-PCR	GenScript[84,89,90] USA	29 Jan 2020	**qRT-PCR** Targets RdRP gene, N gene and E gene in Wuhan-Hu-1 genome (GenBank sequences NC_045512.2) [same as Charite's first protocol]	"This assay is RUO and has not been tested on clinical samples. We make no claims on the performance of this assay." [89]	"This assay may have cross-reactivity with other coronavirus family members such as causative agents of the Middle East Respiratory Syndrome (MERS) or Severe Acute Respiratory Syndrome (SARS)."[89]	Commercially available for RUO.	(no info)	(by quote)
Next-generation sequencing (NGS)	IDbyDNA[91,92] USA	29 Jan 2020	Next-generation sequencing (NGS)-based metagenomics, allows enhanced pathogen detection and profiling in comparison to conventional PCR testing.[92]	(no info)	(no info)	Commercially available.	(no info)	(by quote)
Real-time RT-RAA	Beijing Ditan Hospital[93] China	29 Jan 2020	**Real time Reverse-Transcription Recombinase Aided Amplification (RT-RAA) assay** Novel isothermal nucleic acid amplification technique for detection of SARS-CoV-2. Assay was performed at 42°C within 30min using a portable real-time fluorescence detector,	(Recombinant plasmids containing conserved ORF1ab genes was used to analyze the specificity and sensitivity.)	(Recombinant plasmids containing conserved ORF1ab genes was used to analyse the specificity and sensitivity.)	Clinical trials phase.	(no info)	(no info)
CRISPR-based diagnostics	Mammoth Biosciences[77,94,95] (Partnering with UCSF Researchers)	30 Jan 2020	**CRISPR**: Using the smaller Cas14 protein instead of usual Cas9 protein. Theoretically, the Cas14 "breaks apart a "reporter molecule," which can then	(no info)	(no info)	In development as of 6 Feb 2020	(no info)	(no info)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
	USA		change the color of the solution, indicating a positive or negative test result."[95]					
Real-time RT-PCR	CerTest Biotec[96] Spain	30 Jan 2020	**VIASURE 2019-nCoV Real Time PCR Kit** Amplification of a fragment of the S gene.[97]	(no info)	(no info)	Available. Received CE Mark for IVD for the version adapted for the BD MAX™ System.[97]	(no info)	(no info)
PCR-based genotyping	Genomica[98,99] Spain	30 Jan 2020	**CLART COVID-19** Based on Genomica's CLART technology of PCR-based genotyping with low-density microarray.	(no info)	(no info)	Available. Received CE Mark 6 Mar 2020.[100]	Less than 5 hours	(no info)
qPCR	Novacyt[101,102] (molecular diagnostics division Primerdesign) France/UK	31 Jan 2020	**qPCR[102]** Can run on multiple molecular testing platforms, including Primerdesign's own genesig® q16 and q32 instrument	(no info)	(no info)	Commercially available. Received CE Mark for IVD 17 Feb 2020.[103,104] Submitted to US FDA for EUA.[103]	Less than 2 hours	
(no info)	Roche[105,106] Switzerland	31 Jan 2020	(no info)	(no info)	(no info)	In development for commercial kit.	(no info)	(no info)
RT-PCR	A*STAR[107,108] (Manufactured by Singapore's MiRxes which has a nonexclusive license)[109] Singapore	1 Feb 2020	**A*STAR Fortitude 2.0** Supports 188 tests per kit	(no info)	(no info)	Available but not for commercial sale yet. Provisional authorization for clinical use from Singapore's Health Sciences Authority.[108,109]	(no info)	(no info)
Real-time RT-PCR	GeneFirst[110] UK	3 Feb 2020	Capable of detecting only the SARS-CoV-2	(no info)	(no info)	Available	Under 3 hours	(no info)
Real-time RT-PCR	GeneFirst[110] UK	3 Feb 2020	Multiplex assay which simultaneously detects SARS-CoV-2 as well as 17 other common viruses and bacteria	(no info)	(no info)	Available.	Under 3 hours	(no info)
(no info)	TCM Biosciences[111]	3 Feb 2020	**TCM-Q Corona Ⅲ**	(no info)	(no info)	Developed as of 3 Feb 2020.	(no info)	(no info)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
	South Korea					Submitted to Korean CDC for EUA.		
Real-time RT-PCR	Kogene Biotech[111,112] South Korea	3 Feb 2020	**Powerchek 2019-nCoV Real-time PCR kit** Tests for two gene targets: E and RDRP.	(no info)	(no info)	Commercially available. Obtained EUA approval from Korean CDC 4 Feb 2020.[112,113]	(no info)	(no info)
(no info)	PCL[111] South Korea	3 Feb 2020	**Multiplex diagnostic kit**	(no info)	(no info)	Developed as of 3 Feb 2020.	(no info)	(no info)
(no info)	Bioneer[111] South Korea	3 Feb 2020	(no info)	(no info)	(no info)	Assumed developed as of 3 Feb 2020. Submitted to Korean CDC for EUA.	(no info)	(no info)
(no info)	Lab Geneomics[111] South Korea	3 Feb 2020	(no info)	(no info)	(no info)	Undergoing commercialisation as of 6 Feb 2020	(no info)	(no info)
(no info)	CEVI[111] (Partnership with Wells Bio) South Korea	3 Feb 2020	(no info)	(no info)	(no info)	In development as of 6 Feb 2020	(no info)	(no info)
Enzyme-assisted nanocomplex	iHealthtech[72,114] (Asst Prof Shao Huilin) Singapore	3 Feb 2020	**enVision (enzyme-assisted nanocomplexes for visual identification of nucleic acids)** Uses enzyme-assisted nanocomplexes	(no info)	(no info)	In development.	30 min	(no info)
RT-PCR	Biomeme[115,116] USA	4 Feb 2020	Shelf-stable strip with 3 reaction wells, each reaction contains lyophilized master mix, multiplexed primers, and probes for the following triplex: - 2019-nCoV-Orf1ab - 2019-nCoV-S - MS2 bacteriophage as an RNA extraction and RT-PCR control	(no info)	(no info)	Commercially available.	(no info)	$300 for 10 strips + $5,950 for PCR Thermocycler + $450 for sample prep kit
Conventional and Real Time RT-PCR	Genekam[117,118] Germany	4 Feb 2020	5 options: 1. Conventional PCR 2. Real Time PCR for nCoV only[119] 3. Multiplex Real Time PCR for nCoV + other Bat CoV[120]	(no info)	(no info)	In development as of 6 Feb 2020	126 min 15 s[119,121] or 120 min[120,122] of cycle time	€ 599[118] € 699[118] € 799[118] € 999[118] € 899[118]

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			4. Multiplex Real Time PCR for nCoV + other Bat CoV + MERS[121] 5. Multiplex Real Time PCR for nCoV + Influenza A[122]					
Real-time RT-PCR	Thermo Fisher Scientific[115,123] USA	4 Feb 2020	**TaqMan 2019-nCoV Assay Kit** Real-time RT-PCR kit assays specifically target all 44 complete genomes currently available at GISAID, and do not target any of the 2,116 complete genomes of other coronaviruses currently available at NCBIm covering orf1ab, spike (S) gene, nucleocapsid (N) gene)	(no info)	(no info)	Available to order but only ready in late February.[115]	(no info)	(by quote)
Real-time RT-PCR	US CDC[13] USA	4 Feb 2020	**Centers for Disease Control and Prevention (CDC) 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel** Tests for three N gene targets and 1 human RNase P gene control	(no info)	Quality control issues with reagents pertaining to detection of the N3 assay for universal detection of SARS-like coronaviruses.[14]	Available to laboratories designated by CDC as qualified, and in the US, certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high complexity tests. Available to qualified international laboratories. Not available to U.S. hospitals or other primary care settings. Obtained EUA approval from US FDA 4 Feb 2020.	(no info)	(no info)
RT-PCR	Livzon[124]	4 Feb 2020	**Novel coronavirus (2019-nCoV) nucleic acid diagnostic kit (PCR-fluorescence method)** Detection of ORF1ab and N genes.	(no info)	(no info)	Developed. Undergoing testing. Emergency use approval submitted to China National Medical Products Administration on 27 Jan 2020	(no info)	(no info)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
IgM/IgG antibody immunoassay (ELISA)	Livzon[124] (collaboration with Wuhan Institute of Virology, Chinese Academy of Science)	4 Feb 2020	**Diagnostics kit for IgM/IgG antibody to novel coronavirus (ELISA)** Indirect method for ELISA for in vitro qualitative detection of antibodies to SARS-CoV-2 in human serum or plasma.	(no info)	(no info)	Developed. Undergoing testing. Emergency use approval submitted to China National Medical Products Administration on 28 Jan 2020.	(no info)	(no info)
IgM/IgG antibody immunoassay (colloidal gold)	Livzon[124] (collaboration with Wuhan Institute of Virology, Chinese Academy of Science)	4 Feb 2020	**Diagnostics kit for IgM/IgG antibody to novel coronavirus (colloidal gold)** Immunochromatography assay for in vitro qualitative detection of antibodies to SARS-CoV-2 in human serum or plasma.	(no info)	(no info)	Developed. Undergoing testing. Emergency use approval submitted to China National Medical Products Administration on 2 Feb 2020.	15 min	(no info)
qPCR	Coyote Bioscience[79,115] China	4 Feb 2020	**2019-nCoV Prep Free QPCR Assay** Runs on the Mini8 Portable Molecular Diagnostic QPCR Station (CFDA approved)	(no info)	(no info)	Available. Reportedly being used in China in over 30 hospitals, 16 local CDC offices, and 8 airports.	1 hr	(no info)
Microfluidic	Shenzhen Shineway Technology[125,126] (collaboration with HKUST) Hong Kong	6 Feb 2020	Novel silicon-based micro-heater, which has lower thermal mass and a better thermal conductivity, could speed up temperature rises to around 30^{o}C per second, greatly reducing the detection time compared to conventional PCR devices which has an average of 4-5^{o}C per second.	(no info)	(no info)	Available. In use by the Centers for Disease Control and Prevention (CDCP) in Shenzhen and Guangzhou with two more sets being delivered to the CDCP in Hubei and Nansha.[126] Device already has CE Mark and is qualified for export to all European Union (EU) countries as well as Hong Kong.[125]	40 min	(no info)
RT-PCR	Acumen Research Laboratories[127] Singapore	7 Feb 2020	**RT-PCR** With specific gene targets.	(no info)	(no info)	Prototype developed.	About 2 hours.	(no info)
Microfluidic	Qiagen[128] The Netherlands	10 Feb 2020	**QiaStat-Dx Respiratory Panel [Plus]** Tests for two gene targets: ORF1b recommended by	(no info)	(no info)	Expected to be developed by Feb 2020.	Would be faster than RT-PCR.	(no info)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			the Chinese CDC and N recommended by the US CDC.					
(no info)	Public Health England[129] UK	10 Feb 2020	(no info)	(no info)	(no info)	Available (non-commercially) to 12 labs across the UK.	(no info)	(no info)
RT-PCR [Point-of-Care]	Cepheid[130] (Plus collaboration with Sherlock Biosciences)[80] USA	10 Feb 2020	**GeneXpert system** Cartridge-based nucleic acid amplification test	(no info)	(no info)	In development.	30 min	(no info)
Real-time PCR and microarray technologies [Point-of-Care]	Mobidiag[131] (collaboration with Autobio Diagnostics, China) Finland	10 Feb 2020	**Novodiag** Cartridge-based qPCR system, fully automated, allowing the rapid detection of both novel coronavirus and influenzas in around 30 minutes.	(no info)	(no info)	In development.	30 min	(no info)
Immunoassay [Point-of-Care]	Sona Nanotech[132] (collaboration with The Native Antigen Company)[133] Canada	10 Feb 2020	Proprietary nanotechnology lateral flow test using antigens specific to SARS-CoV-2 produced at Native's Oxford facility using proprietary mammalian VirtuE expression system.	(no info)	(no info)	In development.	5-15 min	<$50
LAMP [Point-of-Care]	HiberGene Diagnostics[134,135] (collaboration with distribution partner in Shenzhen, China, Medcaptain Medical Technologies) Ireland	11 Feb 2020	**Loop-mediated isothermal amplification (LAMP)-based Coronavirus test** Allows for rapid near-patient testing	(no info)	(no info)	In development using the template of existing CE-marked Flu and RSV respiratory tests.	60-70 min (including patient sample preparation time)[135]	(no info)
(no info) [Point-of-Care]	QuantuMDx[79] UK	12 Feb 2020	(no info)	(no info)	(no info)	(no info)	(no info)	(no info)
qPCR [Point-of-Care]	Molbio Diagnostics[79] India	12 Feb 2020	Potentially real-time PCR then detection of wavelengths of fluorescent signal.	(no info)	(no info)	In development using existing TrueLab System.	55 min	(no info)
qPCR	OnSiteGene[79]	12 Feb 2020	2019-nCoV rRT-PCR kit for use on existing Peak V, that	(no info)	(no info)	In development.	10 min	(no info)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
[Point-of-Care]	(San Diego-based subsidiary of Singapore's Star Array) USA		performs spatial thermal cycling using a heated liquid metal for direct amplification without the need for sample prep.					
CLIA	Shenzhen Tisenc Medical Device[34] (collaboration with Shenzhen University and Shenzhen No.3 People's Hospital) China	12 Feb 2020	Chemiluminescence antibody test kit using serum or plasma.	(no info)	(no info)	Developed and tested but not commercially available yet.	22 min (unclear if serum/plasma extraction time included or not)	(no info)
RT-PCR	TIB-Molbiol[106,136] (distributed by Roche) Germany	12 Feb 2020	**2019-nCoV Real-Time Reverse Transcription PCR Kit** Tests for three gene targets: E, RdRP, and N.	(no info)	(no info)	Available for RUO.	(no info)	(no info)
IgM antibody immunoassay [Point-of-Care]	Guangzhou Medical University[7,22] (Dr Zhong Nanshan) China	15 Feb 2020	IgM antibody detection kit.	(no info)	(no info)	Available for use in China but not commercially	15 min (unclear if serum/plasma extraction time included or not)	(no info)
IgM/IgG antibody immunoassay	Nankai University[35] China	17 Feb 2020	**Novel Coronavirus (2019-nCoV) IgM/IgG antibody detection kit**	(no info)	(no info)	Developed but not commercially available yet.	15 min (unclear if serum/plasma extraction time included or not)	(no info)
RT-PCR	Seegene[137,138] South Korea	18 Feb 2020	**Allplex 2019-nCoV Assay** Single-tube assay that tests for three gene targets: E, RdRP, and N.	(no info)	(no info)	Commercially available. Obtained EUA approval from Korean FDA 12 Feb 2020.[112,139] Product already has CE Mark for IVD.	(no info)	(no info)
IgM and IgG antibody immunoassay [Point-of-Care]	Guangzhou Wondfo Biotech[23-27] China	20 Feb 2020	**Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method)**	(no info)	(no info)	Available. Approved by the China National	15 min (unclear if serum/plasma extraction time included or not)	(no info)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			Colloidal gold method for IgM and IgG antibody detection.			Medical Products Administration. Received CE Mark Mar 2020.[27,28]		
IgG and IgA antibody immunoassay	EUROIMMUN AG[140-142] Germany	21 Feb 2020	ELISA for IgG and IgA antibody detection.	(no info)	(no info)	Commercially available. Not available as IVD in the EU.[140]	(no info)	(no info)
IgG and IgM antibody immunoassay [Point-of-Care]	Jiangsu Medomics Medical Technology[33,36] China	21 Feb 2020	Lateral flow immunoassay with both IgM and IgG antibodies adhered using colloidal gold. Can be used with fingerstick whole blood.	**88.66%** 352 positive out of 397 positive cases: - 256 both IgG and IgM - 72 IgG - 24 IgM	**90.63%** 12 positive out of 128 negative controls: - 1 both IgG and IgM - 1 IgG - 10 IgM	Available.	15 min	(no info)
IgM antibody immunoassay	Innovita Biological Technology[23] China	23 Feb 2020	IgM antibody detection.	(no info)	(no info)	Available. Approved by the China National Medical Products Administration.	(no info)	(no info)
(RT-PCR)	CapitalBio[24] (collaboration with Tsinghua University and West China Hospital of Sichuan University) China	24 Feb 2020	Detection of six common respiratory viruses including SARS-CoV-2 within 1.5 hours using samples of patients' oral and pharyngeal Secretions.	(no info)	(no info)	Available. Approved by the China National Medical Products Administration.	1 hr 30 min	(no info)
IgM or IgG antibody immunoassay	Duke-NUS Medical School[20,21] (Prof Wang Linfa) Singapore	26 Feb 2020	IgM or IgG antibody detection.	(no info)	(no info)	Available (not commercially).	(no info)	(no info)
Real-time RT-PCR	SolGent[112,139,143] South Korea	28 Feb 2020	**DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit** Tests for two gene targets: Orf1a and N.	(no info)	(no info)	Commercially available. Obtained EUA approval from Korean CDC 27 Feb 2020.[112,139] Received CE Mark for IVD.	120 min PCR	(no info)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
Real-time RT-PCR	SD Biosensor[112,139] South Korea	28 Feb 2020	**STANDARD M n-CoV Real-Time Detection Kit** Tests for two gene targets: E and RdRP.	(no info)	(no info)	Available. Obtained EUA approval from Korean CDC 27 Feb 2020.[112,139]	6 hr	(no info)
CLIA for IgM and IgG antibody	Snibe Diagnostic[144,145] China	28 Feb 2020	**Maglumi 2019-nCoV (SARS-CoV-2) IgM/IgG kits** Fully automated CLIA using 10µL sample volume of serum or plasma.	(no info)	(no info)	Available. Have been distributed in China and will soon be in Italy. Received CE Mark 19 Feb 2020.[145]	30 min	(no info)
RT-PCR	Osang Healthcare[146,147] (partnership with Italy's ELITech Group) South Korea	3 Mar 2020	**GeneFinder COVID-19 Plus RealAmp Kit** Tests for three gene targets: RdRP, E, and N. Runs on all major PCR cyclers as well as on the Sample-to-Result Platform ELITe InGenius.	(no info)	(no info)	Available. Received CE Mark for IVD.	(no info)	(no info)
Real-time RT-PCR	Integrated DNA Technologies (IDT)[148,149] USA	3 Mar 2020	**2019-nCoV CDC EUA Kit** Follows US CDC protocol to test for 3 N gene targets, and 1 human RNase P gene as control.	(no info)	(no info)	Commercially available. Obtained EUA approval from US FDA 3 Mar 2020.		USD $125[149] for 500 rxn
Real-time RT-PCR	Genomica[100,150] Spain	6 Mar 2020	**qCOVID-19** Real-time RT-PCR	Reported **100%.**[150] Tested at the Carlos III Health Institute with 80 samples (unclear of sample types).	Reported **100%.**[150] Tested at the Carlos III Health Institute with 80 samples (unclear of sample types).	Available. Received CE Mark 6 Mar 2020.[100]	(no info)	(no info)
IgM and IgG antibody immunoassay [Point-of-Care]	Pharmact AG[29] Germany	10 Mar 2020	**CoV-2 Rapid Test** Using drops of blood from fingerstick onto test cassette, with two drops of buffer solution .	(no info)	(no info)	Available.	20 min	€39.95
IgM and IgG antibody immunoassay [Point-of-Care]	Zhejiang Orient Gene Biotech[30,31] China	10 Mar 2020	**COVID-19 IgG/IgM Rapid Test** Solid phase immunochromatography assay for rapid qualitative detection of IgG and IgM antibodies to SARS-CoV-2	IgM test **87.9%** (87/99) IgG test **97.2%** (35/36) Tested with 113 blood samples, and the results compared to RT-PCR or clinical diagnosis.	IgM test **100%** (14/14) IgG test **100%** (14/14) Tested with 113 blood samples, and the results compared to RT-PCR or clinical diagnosis.	Available. Received CE Mark. Currently one of only a few tests used for coronavirus screening in China.	2-10 min	(no info)

Type	Organisation	Reported	Test	Sensitivity	Specificity	Availability	Turnaround	Costs
			using human whole blood, serum or plasma.			Commercialisation and distribution licensing deal with Aytu Bioscience for USA.		
Real-time RT-PCR	Wadsworth Center, New York State Department of Public Health[151] USA	10 Mar 2020	**New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel**	(no info)	(no info)	Available. Obtained EUA approval from US FDA for use in Wadsworth Center, New York State Public Department of Health, and the New York City Department of Health and Mental Hygiene, Public Health Laboratories.	(no info)	(no info)
IgM and IgG antibody immunoassay [Point-of-Care]	SD Biosensor[32] South Korea	(12 Mar 2020)	**STANDARD Q COVID-19 IgM/IgG Duo** Immunochromatography assay for rapid qualitative detection of IgG and IgM antibodies to SARS-CoV-2 using human whole blood, serum or plasma.	(no info)	**95%** (95/100)	Available.	10 min	(no info)

RT-PCR: reverse transcription polymerase chain reaction
LAMP: loop-mediated isothermal amplification
CLIA: chemiluminescence immunoassay
IgM: Immunoglobulin M
IgG: Immunoglobulin G
IgA: Immunoglobulin A
RUO: Research Use Only
IVD: In Vitro Diagnostics
EUA: emergency use assessment
CE Mark: Conformitè Europëenne (CE) Mark – European Union's mandatory conformity marking for regulating goods sold in European Economic Area
rxn: reactions

Table 3. Approaches for Coronavirus Diagnostics

Type	Test	Coronavirus	Sensitivity	Specificity	Availability	Turnaround	Costs
RT-PCR	Duplex RT-PCR method with primers and probes targeting: pUC57SARS-pS2	SARS-CoV					
RT-PCR	Duplex RT-PCR method with primers and probes targeting: pGEM-MERSS2	MERS-CoV					
RT-PCR	Singleplex RT-iiPCR assays targeting open reading frame 1a gene: MERS-CoV ORF1a	MERS-CoV	99.3%	(no info)			
RT-PCR	Singleplex RT-iiPCR assays targeting envelope gene: upE RT-iiPCR	MERS-CoV	100%	(no info)			
rRT-PCR	AccuPower (Bioneer, Korea) Two single gene-targeting reagents for simultaneous detection of upE and ORF1a genes	MERS-CoV	100%	100%	Commercial kit		
rRT-PCR	Anyplex (Seegene, Korea) Screening: Single gene target of upstream of upE region Confirmation: Multiple gene targets at both upE and ORF1a regions	MERS-CoV	100%	100%	Commercial kit		
rRT-PCR	DiaPlexQ (SolGent, Korea) Screening: Single gene target of upstream of upE region Confirmation: Multiple gene targets at both upE and ORF1a regions	MERS-CoV	100%	100%	Commercial kit		
rRT-PCR	LightMix (Roche Molecular Diagnostics, Switzerland) Two single gene-targeting reagents for simultaneous detection of upE and ORF1a genes	MERS-CoV	100%	100%	Commercial kit		
rRT-PCR	UltraFast kits (Nanobiosys, Korea) Two single gene-targeting reagents for simultaneous detection of upE and ORF1a genes	MERS-CoV	100%	100%	Commercial kit		
rRT-PCR	PowerChek (Kogene Biotech, Korea) Screening: Single gene target of upstream of upE region Confirmation: Multiple gene targets at both upE and ORF1a regions	MERS-CoV	100%	100%	Commercial kit		
rRT-PCR	TaqMan probe-based one-step rRT-PCR assays for upE and ORF1b genes.	MERS-CoV					
rRT-PCR	Monoclonal antibodies-based rapid nucleoprotein assay	MERS-CoV	Detection limit of about 103.7-104.2 $TCID^{50}$/ml of MERS-CoV				
RT-LAMP	Two primer sets with one targeting the N gene and one targeting the ORF1a gene	MERS-CoV					
RT-LAMP-VF	Two primer sets with one targeting the N gene and one targeting the ORF1a gene combined with vertical flow visualization strip using nucleic acid visualization technique.	MERS-CoV		No cross-reactivity to multiple SARS-related-CoVs, including HKU1, HKU4, OC43 and 229E.			
(novel)	Arch-shaped multiple-target sensor	MERS-CoV				20 min	

RT-PCR: reverse transcription polymerase chain reaction
rRT-PCR: real-time reverse transcription polymerase chain reaction
RT-LAMP: reverse transcription loop-mediated isothermal amplification
RT-LAMP-VF: reverse transcription loop-mediated isothermal amplification with a vertical flow visualization strip
upE: envelope gene
ORF1a: open reading frame 1a
ORF1b: open reading frame 1b

References

1. Corman VM et al (2020) Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR. *Euro Surveill.*(28 Jan 2020). Available at:
2. Medical Technology (2020) The Importance of Diagnostic Tests in Fighting Infectious Diseases 2020. Available at: https://www.lifechanginginnovation.org/medtech-facts/importance-diagnostic-tests-fighting-infectious-diseases (accessed 28 Jan 2020)
3. Zhang N et al (2020) Recent advances in the detection of respiratory virus infection in humans. *J Med Virol.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/31944312
4. World Health Organization (2020) Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases - Interim Guidance 2020. 17 Jan 2020. Available at: https://www.who.int/healthtopics/coronavirus/laboratory-diagnostics-for-novel-coronavirus. (accessed 28 Jan 2020)
5. World Health Organization (2020) Novel Coronavirus (2019-nCoV) technical guidance: Laboratory testing for 2019-nCoV in humans. 31 Jan 2020. Available at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance (accessed 31 Jan 2020)
6. Institut Pasteur (2020) Protocol: Real-time RT-PCR assays for the detection of SARS-CoV-2. 02 Mar 2020. Available at: https://www.who.int/docs/default-source/coronaviruse/real-time-rt-pcr-assays-for-the-detection-of-sars-cov-2-institut-pasteur-paris.pdf?sfvrsn=3662fcb6_2 (accessed 09 Mar 2020)
7. Liu D et al (2020) China Applies Stricter Criteria for Diagnosing Covid-19 Cases. Caixin. 20 Feb 2020. Available at: https://www.caixinglobal.com/2020-02-20/china-applies-stricter-criteria-for-diagnosing-covid-19-cases-101517843.html (accessed 20 Feb 2020)
8. Charité Virology (2020) Diagnostic detection of Wuhan coronavirus 2019 (17 Jan 2019). 17 Jan 2020. Available at: https://www.who.int/docs/default-source/coronaviruse/protocol-v2-1.pdf?sfvrsn=a9ef618c_2 (accessed 28 Jan 2020)
9. School of Public Health The University of Hong Kong (2020) Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR. 16 Jan 2020. Available at: https://www.who.int/docs/default-source/coronaviruse/peiris-protocol-16-1-20.pdf?sfvrsn=af1aac73_4 (accessed 28 Jan 2020)
10. Chu DKW et al (2020) Molecular Diagnosis of a Novel Coronavirus (2019-nCoV) Causing an Outbreak of Pneumonia. *Clin Chem.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32031583
11. U.S. Department of Health & Human Services (2020) Real-Time RT-PCR Panel for Detection 2019-Novel Coronavirus. 24 Jan 2020. Available at: https://www.cdc.gov/coronavirus/2019-ncov/downloads/rt-pcr-panel-for-detection-instructions.pdf (accessed 28 Jan 2020)
12. U.S. Department of Health & Human Services (2020) 2019-Novel Coronavirus (2019-nCoV) Real-time rRT-PCR Panel Primers and Probes. 24 Jan 2020. Available at: https://www.cdc.gov/coronavirus/2019-ncov/downloads/rt-pcr-panel-primer-probes.pdf (accessed 28 Jan 2020)
13. U.S. Department of Health & Human Services (2020) CDC Tests for 2019-nCoV. 05 Feb 2020. Available at: https://www.cdc.gov/coronavirus/2019-ncov/about/testing.html (accessed 10 Feb 2020)
14. Johnson M (2020) Coronavirus Test Kits Encounter QC Hiccup in Some States, CDC Reports. GenomeWeb. 12 Feb 2020 Available at: https://www.genomeweb.com/pcr/coronavirus-test-kits-encounter-qc-hiccup-some-states-cdc-reports#.XkTV2VIzYcg (accessed 13 Feb 2020)
15. Feuer W (2020) Amid testing capacity concerns, CDC unveils new coronavirus test kits. CNBC. 28 Feb 2020. Available at: https://www.cnbc.com/2020/02/28/amid-testing-capacity-concerns-cdc-unveils-new-coronavirus-test-kits.html (accessed 03 Mar 2020)
16. Chuck E (2020) After missteps, CDC says its coronavirus test kit is ready for primetime. CNBC. 29 Feb 2020. Available at: https://www.nbcnews.com/health/health-news/after-missteps-cdc-says-its-coronavirus-test-kit-ready-primetime-n1145206 (accessed 03 Mar 2020)
17. Lim D et al (2020) U.S. health officials probe coronavirus test problems at CDC. Politico. Available at: https://www.politico.com/news/2020/03/01/health-officials-probe-coronavirus-cdc-118523 (accessed 03 Mar 2020)
18. Swan J et al (2020) Scoop: CDC lab for coronavirus test kits may have been contaminated. Axios. 01 Mar 2020. Available at: https://www.axios.com/cdc-lab-coronavirus-contaminated-6dc9726d-dea3-423f-b5ad-eb7b1e44c2e2.html (accessed 02 Mar 2020)

19. U.S. Food and Drug Administration (2020) Coronavirus (COVID-19) Update: FDA Issues New Policy to Help Expedite Availability of Diagnostics. 29 Feb 2020. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics (accessed 03 Mar 2020)
20. Channel News Asia (2020) Duke-NUS used COVID-19 antibody tests to establish link between church clusters in a world-first. 26 Feb 2020. Available at: https://www.channelnewsasia.com/news/singapore/covid19-coronavirus-duke-nus-antibody-tests-12469184 (accessed 26 Feb 2020)
21. Chew E (2020) Singapore Researchers Make Advances in Coronavirus Test Method. Bloomberg. 26 Feb 2020. Available at: https://www.bloomberg.com/news/articles/2020-02-26/singapore-researchers-make-breakthrough-in-coronavirus-testing (accessed 26 Feb 2020)
22. Cao Q (2020) China develops COVID-19 detection kit that delivers results in 15 minutes. CGTN. CGTN. 15 Feb 2020. Available at: https://news.cgtn.com/news/2020-02-15/China-develops-COVID-19-detection-kit-that-delivers-results-in-15-min--O6aPGKuzGo/index.html (accessed 20 Feb 2020)
23. Global Times (2020) New COVID-19 drugs approved for fast and accurate diagnosis: China's top epidemiologist. 23 Feb 2020. Available at: http://www.globaltimes.cn/content/1180544.shtml (accessed 26 Feb 2020)
24. Gao Y (2020) China greenlights new testing kits to identify COVID-19. CGTN. 24 Feb 2020. Available at: https://news.cgtn.com/news/2020-02-24/China-greenlights-new-testing-kits-to-identify-COVID-19-Ol9QqDDWRa/index.html (accessed 26 Feb 2020)
25. GBI Source (2020) Wondfo Bio's 2 coronavirus detection kits super fast-track in China. 20 Feb 2020. Available at: https://source.gbihealth.com/News/NewsDetail?newsID=2033702&newsType=news (accessed 26 Feb 2020)
26. Qiu Q (2020) China greenlights new coronavirus detection method. 23 Feb 2020. Available at: https://www.chinadaily.com.cn/a/202002/23/WS5e528b42a3101282172799b6.html (accessed 26 Feb 2020)
27. Guangzhou Wondfo Biotech (2020) Guangzhou Wondfo Biotech's New Coronavirus Test Products Receive CE Mark. 06 Mar 2020. Available at: http://www.szse.cn/disclosure/listed/bulletinDetail/index.html?445b33ef-b062-46f0-9a1a-0801d94c1dc9 (accessed 12 Mar 2020)
28. Reuters (2020) Guangzhou Wondfo Biotech's Three New Coronavirus Test Products Receive CE Mark, Qualified To Enter EU Market. 06 Mar 2020. Available at: https://www.reuters.com/article/brief-guangzhou-wondfo-biotechs-three-ne/brief-guangzhou-wondfo-biotechs-three-new-coronavirus-test-products-receive-ce-mark-qualified-to-enter-eu-market-idUSL4N2AZ2WK (accessed 12 Mar 2020)
29. PR Newswire (2020) German Company Pharmact AG Develops a Point-of-Care Rapid Test for the Detection of the Coronavirus (SARS-CoV-2). 10 Mar 2020. Available at: https://www.prnewswire.com/news-releases/german-company-pharmact-ag-develops-a-point-of-care-rapid-test-for-the-detection-of-the-coronavirus-sars-cov-2-301020339.html (accessed 11 Mar 2020)
30. 360Dx (2020) Aytu BioScience Licenses US Rights to Point-of-Care Coronavirus Test. 10 Mar 2020. Available at: https://www.360dx.com/infectious-disease/aytu-bioscience-licenses-us-rights-point-care-coronavirus-test#.XmhTLKgzaUk (accessed 11 Mar 2020)
31. Accesswire (2020) Aytu BioScience Secures Exclusive U.S. Distribution Agreement for Coronavirus 2019 (COVID-19) Point-of-Care Rapid Test. 10 Mar 2020. Available at: https://www.accesswire.com/579898/Aytu-BioScience-Secures-Exclusive-US-Distribution-Agreement-for-Coronavirus-2019-COVID-19-Point-of-Care-Rapid-Test (accessed 11 Mar 2020)
32. SD Biosensor (2020) STANDARD Q COVID-19 IgM IgG Duo. Available at: http://sdbiosensor.com/xe/product/7662 (accessed 12 Mar 2020)
33. Xinhua (2020) Chinese researchers develop rapid antibody test kit for coronavirus. 21 Feb 2020. Available at: http://www.xinhuanet.com/english/2020-02/21/c_138805748.htm (accessed 09 Mar 2020)
34. China Plus (2020) Researchers develop quick test for novel coronavirus. 12 Feb 2020. Available at: http://chinaplus.cri.cn/recommended/1661/419776 (accessed 20 Feb 2020)
35. Xinhua (2020) Chinese university develops rapid test kit for novel coronavirus 17 Feb 2020. Available at: www.xinhuanet.com/english/2020-02/17/c_138791386.htm (accessed 18 Feb 2020)

36. Li Z et al (2020) Development and Clinical Application of A Rapid IgM-IgG Combined Antibody Test for SARS-CoV-2 Infection Diagnosis. *J Med Virol.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32104917
37. Patton D et al (2020) China's Hubei province sees surge in coronavirus deaths on switch to new methodology. Reuters. Available at:
38. Chung M et al (2020) CT Imaging Features of 2019 Novel Coronavirus (2019-nCoV). *Radiology.*200230. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32017661
39. Bernheim A et al (2020) Chest CT Findings in Coronavirus Disease-19 (COVID-19): Relationship to Duration of Infection. *Radiology.*200463. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32077789
40. Ai T et al (2020) Correlation of Chest CT and RT-PCR Testing in Coronavirus Disease 2019 (COVID-19) in China: A Report of 1014 Cases. *Radiology.*200642. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32101510
41. Shi H et al (2020) Radiological findings from 81 patients with COVID-19 pneumonia in Wuhan, China: a descriptive study. *Lancet Infect Dis.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32105637
42. Xie X et al (2020) Chest CT for Typical 2019-nCoV Pneumonia: Relationship to Negative RT-PCR Testing. *Radiology.*200343. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32049601
43. Sun H (2020) Alibaba says AI can identify coronavirus infections with 96% accuracy Nikkei Asian Review. 19 Feb 2020. Available at: https://asia.nikkei.com/Spotlight/Coronavirus/Alibaba-says-AI-can-identify-coronavirus-infections-with-96-accuracy (accessed 20 Feb 2020)
44. Kim C et al (2011) Comparison of nasopharyngeal and oropharyngeal swabs for the diagnosis of eight respiratory viruses by real-time reverse transcription-PCR assays. *PLoS One.*6(6):e21610. Available at: https://www.ncbi.nlm.nih.gov/pubmed/21738731
45. Kelly-Cirino C et al (2019) An updated roadmap for MERS-CoV research and product development: focus on diagnostics. *BMJ Glob Health.*4(Suppl 2):e001105. Available at: https://www.ncbi.nlm.nih.gov/pubmed/30815285
46. Public Health Laboratory Network (2020) PHLN guidance on laboratory testing for 2019-nCoV 2020. Jan 2020. Available at: https://www.health.gov.au/sites/default/files/documents/2020/01/phln-guidance-on-laboratory-testing-for-2019-ncov-phln-guidance-on-laboratory-testing-for-novel-coronavirus-2019-ncov.pdf (accessed 28 Jan 2020)
47. U.S. Department of Health & Human Services (2020) Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19). 14 Feb 2020. Available at: https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html (accessed 18 Feb 2020)
48. Jin YH et al (2020) A rapid advice guideline for the diagnosis and treatment of 2019 novel coronavirus (2019-nCoV) infected pneumonia (standard version). *Mil Med Res.*7(1):4. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32029004
49. Yang Y et al (2020) Laboratory diagnosis and monitoring the viral shedding of 2019-nCoV infections. *medRxiv.* Available at:
50. To KK et al (2020) Consistent detection of 2019 novel coronavirus in saliva. *Clin Infect Dis.* Available at: https://www.ncbi.nlm.nih.gov/pubmed/32047895
51. Charité Virology (2020) Diagnostic detection of Wuhan coronavirus 2019 (13 Jan 2019). 13 Jan 2020. Available at: https://www.who.int/docs/default-source/coronaviruse/wuhan-virus-assay-v1991527e5122341d99287a1b17c111902.pdf?sfvrsn=d381fc88_2 (accessed 28 Jan 2020)
52. Chinese Center for Disease Control and Prevention (2020) Specific primers and probes for detection 2019 novel coronavirus. 21 Jan 2020. Available at: http://ivdc.chinacdc.cn/kyjz/202001/t20200121_211337.html (accessed 28 Jan 2020)
53. Department of Medical Sciences Ministry of Public Health Thailand (2020) Conventional RT-PCR for Detection of nCoV. Jan 2020. Available at: https://www.who.int/docs/default-source/coronaviruse/conventional-rt-pcr-followed-by-sequencing-for-detection-of-ncov-rirl-nat-inst-health-t.pdf (accessed 28 Jan 2020)
54. Nao N et al (2020) Detection of second case of 2019-nCoV infection in Japan (corrected version). 23 Jan 2020. Available at: https://www.who.int/docs/default-

source/coronaviruse/method-niid-20200123-2.pdf?sfvrsn=fbf75320_7 (accessed 28 Jan 2020)
55. Genesig (2020) Novel Coronavirus Strain 2019-nCoV. Available at: https://www.genesig.com/products/10037-novel-coronavirus-strain-2019-ncov (accessed 30 Jan 2020)
56. Genesig (2020) Coronavirus (COVID-19) CE IVD. Available at: https://www.genesig.com/products/10039-coronavirus-covid-19-ce-ivd (accessed 12 Mar 2020)
57. Today (2020) BRIEF-Jiangsu Bioperfectus Technologies Develops Test Kit For New China Coronavirus. 14 Jan 2020. Available at: https://www.todayonline.com/world/brief-jiangsu-bioperfectus-technologies-develops-test-kit-new-china-coronavirus (accessed 30 Jan 2020)
58. Oxford Nanopore Technologies (2020) Novel Coronavirus (nCoV-2019). 22 Jan 2020. Available at: https://nanoporetech.com/about-us/news/novel-coronavirus-ncov-2019 (accessed 31 Jan 2020)
59. Johnson M (2020) Diagnostics Developers Leap Into Action on Novel Coronavirus Tests. GenomeWeb. Available at: https://www.genomeweb.com/pcr/diagnostics-developers-leap-action-novel-coronavirus-tests#.XjObEmgzaUk (accessed 30 Jan 2020)
60. Artic Network (2020) About: The Project. Available at: https://artic.network/about.html (accessed 31 Jan 2020)
61. Artic Network (2020) nCoV-2019. Available at: https://artic.network/ncov-2019
62. Co-Diagnostics Inc (2020) Co-Diagnostics Inc Designs Test for New Coronavirus Using CoPrimer Platform. 23 Jan 2020. Available at: http://codiagnostics.com/co-diagnostics-designs-new-coronavirus-test-using-coprimers/ (accessed 30 Jan 2020)
63. Co-Diagnostics Inc (2020) Co-Diagnostics, Inc. Announces Sales of New Coronavirus Test. 10 Feb 2020. Available at: http://codiagnostics.com/co-diagnostics-announces-sales-of-new-coronavirus-test/ (accessed 11 Feb 2020)
64. Genetic Engineering & Biotechnology News (2020) Coronavirus Detection Test in the Works for Wuhan. 24 Jan 2020. Available at: https://www.genengnews.com/news/coronavirus-detection-test-in-the-works-for-wuhan/ (accessed 30 Jan 2020)
65. GenomeWeb (2020) Co-Diagnostics SARS-CoV-2 Assay Garners CE Mark. 24 Feb 2020. Available at: https://www.genomeweb.com/pcr/co-diagnostics-sars-cov-2-assay-garners-ce-mark#.XlXUcSgzaUk (accessed 26 Feb 2020)
66. altona Diagnostics (2020) altona Diagnostics is developing a RT-PCR kit for detection of novel coronavirus (2019-nCoV). 23 Jan 2020. Available at: https://altona-diagnostics.com/en/news/assay-for-novel-coronavirus-under-development.html (accessed 28 Jan 2020)
67. BGI (2020) BGI Develops Real-Time Fluorescent RT-PCR kit for detecting the 2019 Novel Coronavirus. 23 Jan 2020. Available at: https://www.bgi.com/global/company/news/bgi-develops-real-time-dna-based-kit-for-detecting-the-2019-novel-coronavirus/ (accessed 30 Jan 2020)
68. BGI (2020) BGI RT-PCR Kit and PMseq® Solution for Detecting 2019-nCoV. Available at: (accessed 30 Jan 2020)
69. BGI (2020) BGI Receives CE Mark for Novel Coronavirus Test. 02 Mar 2020. Available at: https://www.bgi.com/global/company/news/bgi-receives-ce-mark-for-novel-coronavirus-test/ (accessed 09 Mar 2020)
70. BGI (2020) Real-Time Fluorescent RT-PCR kit for detecting 2019-nCoV. Available at: (accessed 30 Jan 2020)
71. Veredus Laboratories Pte Ltd (2020) Veredus Laboratories Announces the Development of a Lab-on-Chip for the detection of 3 coronaviruses: MERS-CoV, SARS-CoV and 2019-nCoV. 24 Jan 2020. Available at: http://vereduslabs.com/wordpress/wp-content/uploads/2020/01/VereCoV-Press-Release-Final.pdf (accessed 30 Jan 2020)
72. Koh D (2020) iHealthtech researchers working on Wuhan novel coronavirus (2019-nCoV) detection kit. 06 Feb 2020. Available at: https://www.mobihealthnews.com/news/asia-pacific/ihealthtech-researchers-working-wuhan-novel-coronavirus-2019-ncov-detection-kit (accessed 06 Mar 2020)
73. Koh D (2020) Veredus Laboratories' VereCoV detection kit obtains provisional approval for IVD use. MobiHealthNews. 03 Mar 2020. Available at: https://www.mobihealthnews.com/news/asia-pacific/veredus-laboratories-verecov-detection-kit-obtains-provisional-approval-ivd-use (accessed 06 Mar 2020)

74. Yang G (2020) WUHAN VIRUS TEST KIT DEVELOPED BY A SINGAPORE FIRM IS EXPECTED TO BE OUT BY 1 FEB 2020. Goody Feed. Available at: https://goodyfeed.com/wuhan-virus-test-kit/ (accessed 30 Jan 2020)
75. Mohan M (2020) New COVID-19 test kits used to screen swab samples collected at Singapore checkpoints. Channel News Asia. 06 Mar 2020. Available at: https://www.channelnewsasia.com/news/singapore/covid19-new-test-kits-swab-three-hours-12505658 (accessed 11 Mar 2020)
76. Ng RJ (2020) Singapore biotech firm Veredus expects to have Wuhan virus test by Feb 1. The Business Times. 25 Jan 2020. Available at: https://www.businesstimes.com.sg/companies-markets/singapore-biotech-firm-veredus-expects-to-have-wuhan-virus-test-by-feb-1 (accessed 30 Jan 2020)
77. Molteni M (2020) The US Fast-Tracked a Coronavirus Test to Speed Up Diagnoses. WIRED. 04 Feb 2020. Available at: https://www.wired.com/story/the-us-fast-tracked-a-coronavirus-test/ (accessed 05 Feb 2020)
78. Begley S (2020) DNA sleuths read the coronavirus genome, tracing its origins. STAT. 24 Jan 2020. Available at: https://www.statnews.com/2020/01/24/dna-sleuths-read-coronavirus-genome-tracing-origins-and-mutations/ (accessed 06 Feb 2020)
79. Johnson M (2020) Diagnostics Firms Rush to Develop Rapid Point-of-Care Tests for Novel Coronavirus. 360Dx. 12 Feb 2020. Available at: https://www.360dx.com/pcr/diagnostics-firms-rush-develop-rapid-point-care-tests-novel-coronavirus#.Xmsy5KgzaUk (accessed 02 Mar 2020)
80. Cepheid (2020) Cepheid and Sherlock Biosciences Establish Collaboration on New GeneXpert Tests for Infectious Diseases and Oncology Leveraging CRISPR Technology. 28 Feb 2020. Available at: http://cepheid.mediaroom.com/2020-02-28-Cepheid-and-Sherlock-Biosciences-Establish-Collaboration-on-New-GeneXpert-Tests-for-Infectious-Diseases-and-Oncology-Leveraging-CRISPR-Technology (accessed 02 Mar 2020)
81. MIT McGovern Institute (2020) Enabling coronavirus detection using CRISPR-Cas13_ An open-access SHERLOCK research protocol. 14 Feb 2020. Available at: https://mcgovern.mit.edu/2020/02/14/enabling-coronavirus-detection-using-crispr-cas13-an-open-access-sherlock-research-protocol/ (accessed 02 Mar 2020)
82. Zhang F et al (2020) A protocol for detection of COVID-19 using CRISPR diagnostics (v.20200214). 14 Feb 2020. Available at: https://www.broadinstitute.org/files/publications/special/COVID-19%20detection%20(updated).pdf (accessed 18 Feb 2020)
83. LexaGene (2020) LexaGene Analyzer Designed to Detect Pathogens like Coronavirus. 27 Jan 2020. Available at: https://lexagene.com/release/2020/lexagene-analyzer-designed-to-detect-pathogens-like-coronavirus/ (accessed 06 Feb 2020)
84. LeMieux J (2020) Detecting Coronavirus Cases as Outbreak Grows. Genetic Engineering & Biotechnology News,. 29 Jan 2020. Available at: https://www.genengnews.com/news/detecting-coronavirus-cases-as-outbreak-grows/ (accessed 05 Feb 2020)
85. Liferiver Bio-Tech Corp (2020) Novel Coronavirus (2019-nCoV) Real Time RT-PCR Kit. Available at: http://www.liferiverbiotech.com/Pages/Activity.aspx?id=10 (accessed 05 Feb 2020)
86. Antibody-Antibodies.com (2020) Novel Coronavirus (2019-nCoV) Real Time RT-PCR Kit. Available at: https://antibody-antibodies.com/products/rr-0478-02/novel-coronavirus-2019-ncov-real-time-rt-pcr-kit-5235214/ (accessed 05 Feb 2020)
87. Liferiver Bio-Tech Corp (2020) Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit (Detection for 3 Genes). Available at: http://www.liferiverbiotech.com/Pages/Activity.aspx?id=11 (accessed 06 Feb 2020)
88. Antibody-Antibodies.com (2020) Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit (Detection for 3 Genes). Available at: https://antibody-antibodies.com/products/rr-0479-02/novel-coronavirus-2019-ncov-real-time-multiplex-rt-pcr-kit-detection-for-3-genes-5235213/ (accessed 06 Feb 2020)
89. GenScript (2020) 2019-nCoV qRT-PCR Detection Assay. 29 Jan 2020. Available at: https://www.genscript.com/2019-ncov-qrt-pcr-detection-assay.html (accessed 06 Feb 2020)
90. PR Newswire (2020) GenScript Launches Novel Coronavirus Detection Assay. 30 Jan 2020. Available at: https://www.prnewswire.com/news-releases/genscript-launches-novel-coronavirus-detection-assay-300996465.html (accessed 06 Feb 2020)

91. Philippidis A (2020) IDbyDNA to Advance Platform, Now Including Novel Coronavirus, Expand Commercial Operations. Genetic Engineering News. 29 Jan 2020. Available at: https://www.genengnews.com/news/idbydna-to-advance-platform-now-including-novel-coronavirus-expand-commercial-operations/ (accessed 05 Feb 2020)
92. Verdict Medical Devices (2020) IDbyDNA's Explify Respiratory Test can detect coronavirus. Available at: https://www.medicaldevice-network.com/news/idbydnas-explify-respiratory-test-can-detect-coronavirus/ (accessed 06 Feb 2020)
93. Beijing Ditan Hospital (2020) Development of a Simple, Fast and Portable Recombinase Aided Amplification Assay for 2019-nCoV. ClinicalTrials.gov. 29 Jan 2020. Available at: https://clinicaltrials.gov/ct2/show/NCT04245631?recrs=ab&cond=coronavirus&draw=3&rank=5 (accessed 10 Feb 2020)
94. Hyde E (2020) The CRISPR Platform for Next-Generation Therapeutics and Diagnostics. Synbiobeta. 30 Jan 2020. Available at: https://synbiobeta.com/the-crispr-platform-for-next-generation-therapeutics-and-diagnostics/ (accessed 05 Feb 2020)
95. Rosenbaum L (2020) Mammoth Biosciences Raises $45 Million For Crispr Diagnostics—And Its Tech Is Already Being Used Against Coronavirus. Forbes. 30 Jan 2020. Available at: https://www.forbes.com/sites/leahrosenbaum/2020/01/30/mammoth-biosciences-raises-45-million-to-create-crispr-diagnostic-tests-and-its-tech-is-already-being-used-against-coronavirus/#8faec3f56c91 (accessed 05 Feb 2020)
96. CerTest (2020) "We hope to finish shortly the development of a kit to diagnose Wuhan Coronavirus". 30 Jan 2020. Available at: https://www.certest.es/news/we-hope-to-finish-shortly-the-development-of-a-kit-to-diagnose-wuhan-coronavirus/ (accessed 06 Feb 2020)
97. PR Newswire (2020) CerTest Biotec and BD Announce COVID-19 Diagnostic Test. 10 Mar 2020. Available at: https://www.prnewswire.com/news-releases/certest-biotec-and-bd-announce-covid-19-diagnostic-test-301020270.html (accessed 11 Mar 2020)
98. Biospace (2020) GENOMICA, PharmaMar Group, is developing a kit to detect the new Wuhan coronavirus. 30 Jan 2020. Available at: https://www.biospace.com/article/genomica-pharmamar-group-is-developing-a-kit-to-detect-the-new-wuhan-coronavirus/ (accessed 06 Feb 2020)
99. News-Medical (2020) GENOMICA is developing new Wuhan coronavirus diagnostic kit. 31 Jan 2020. Available at: https://www.news-medical.net/news/20200131/GENOMICA-is-developing-new-Wuhan-coronavirus-diagnostic-kit.aspx (accessed 06 Feb 2020)
100. PharmaMar (2020) PharmaMar Group's GENOMICA diagnostic kits for COVID-19 coronavirus receive CE conformity marking. 06 Mar 2020. Available at: http://pharmamar.com/wp-content/uploads/2020/03/PR_diagnostics_kit_covid19_CE_DEF.pdf (accessed 11 Mar 2020)
101. Novacyt (2020) Launch of novel coronavirus test. 31 Jan 2020. Available at: https://novacyt.com/wp-content/uploads/2020/01/Launch-of-novel-coronavirus-test-ENGLISH.pdf (accessed 06 Feb 2020)
102. Bryant M (2020) Novacyt launches test for new coronavirus. 03 Feb 2020. Available at: https://www.bioworld.com/articles/432812-novacyt-launches-test-for-new-coronavirus (accessed 06 Feb 2020)
103. GenomeWeb (2020) Novacyt Gets CE Mark for Coronavirus Test. 18 Feb 2020. Available at: https://www.genomeweb.com/regulatory-news-fda-approvals/novacyt-gets-ce-mark-coronavirus-test#.Xmir9qgzaUk (accessed 09 Mar 2020)
104. Reuters (2020) Novacyt Launches CE-IVD Marked Novel Coronavirus Test. 17 Feb 2020. Available at: https://www.reuters.com/article/brief-novacyt-launches-ce-ivd-marked-nov/brief-novacyt-launches-ce-ivd-marked-novel-coronavirus-test-idUSFWN2AH0JI (accessed 09 Mar 2020)
105. Loh T (2020) Roche's New Coronavirus Test Could Speed Patient Screening. Bloomberg. 31 Jan 2020. Available at: https://www.bloomberg.com/news/articles/2020-01-30/roche-s-new-virus-test-could-speed-up-screening-of-patients (accessed 06 Feb 2020)
106. Roche (2020) Roche statement on 2019-nCoV (novel coronavirus). 31 Jan 2020. Available at: https://www.roche.com/dam/jcr:945deac2-dcbe-4ae0-a7a9-e9b903b142a2/en/roche-statement-on-2019-nCoV.pdf (accessed 06 Feb 2020)
107. Tan A (2020) Coronavirus: Made-in-Singapore diagnostics test rolled out at some hospitals here. The Straits Times. 08 Feb 2020. Available at: https://www.straitstimes.com/singapore/health/coronavirus-made-in-singapore-diagnostics-test-implemented-at-hospitals-here (accessed 10 Feb 2020)

108. Sheridan C (2020) Coronavirus and the race to distribute reliable diagnostics. Nature. 21 Feb 2020. Available at: https://www.nature.com/articles/d41587-020-00002-2 (accessed 26 Feb 2020)
109. GenomeWeb (2020) Singapore Clears New SARS-CoV-2 Assay for Clinical Use. 03 Mar 2020. Available at: https://www.genomeweb.com/pcr/singapore-clears-new-sars-cov-2-assay-clinical-use#.XmirwqgzaUk (accessed 11 Mar 2020)
110. GeneFirst (2020) GeneFirst develops real-time PCR tests for detection of the new coronavirus 2019-nCoV. 03 Feb 2020. Available at: https://www.genefirst.com/copy-of-innovate-shanghai-grant (accessed 06 Feb 2020)
111. Kim S-g et al (2020) Korean firms rush to roll out commercial diagnostic kits for coronavirus. Pulse. 03 Feb 2020. Available at: https://pulsenews.co.kr/view.php?year=2020&no=108967 (accessed 05 Feb 2020)
112. Jeong S-i (2020) Korea approves 2 more COVID-19 detection kits for urgent use. Korea Biomedical Review. 28 Feb 2020. Available at: http://www.koreabiomed.com/news/articleView.html?idxno=7561 (accessed 12 Mar 2020)
113. GenomeWeb (2020) Kogene Biotech Novel Coronavirus Test Gets Regulatory Approvals in Korea. GenomeWeb. 10 Feb 2020. Available at: https://www.genomeweb.com/pcr/kogene-biotech-novel-coronavirus-test-gets-regulatory-approvals-korea#.XkTVuFIzYcg
114. iHealthtech (2020) Developing novel coronavirus rapid detection kit. 03 Feb 2020. Available at: https://ihealthtech.nus.edu.sg/news/developing-novel-coronavirus-rapid-detection-kit/ (accessed 06 Mar 2020)
115. Johnson M (2020) As Worries Grow Over Novel Coronavirus, Dx Industry Jumps Into Action. GenomeWeb. 04 Feb 2020. Available at: https://www.genomeweb.com/pcr/worries-grow-over-novel-coronavirus-dx-industry-jumps-action#.Xjux9GgzaUl (accessed 06 Feb 2020)
116. Biomeme I (2020) COVID-19 Go-Strips. Available at: https://shop.biomeme.com/products/covid-19 (accessed 25 Feb 2020)
117. LabPulse (2020) Germany's Genekam rolls out Wuhan coronavirus test. 04 Feb 2020. Available at: https://www.labpulse.com/index.aspx?sec=sup&sub=mic&pag=dis&ItemID=800737 (accessed 06 Feb 2020)
118. Genekam (2020) Corona Virus 2020 (WUHAN STRAIN)*. 05 Feb 2020. Available at: http://genekam.de/corona-virus-2020-wuhan-strain.php (accessed 06 Feb 2020)
119. Genekam (2020) Fluhunter: Novel Coronavirus 2020 (Wuhan strain specific) –Realtime. Available at: http://genekam.de/manuals/PCR-Realtime/_Ref_FR475-Wuhan%20specific-coronavirus-realtime-single-check.pdf (accessed 06 Feb 2020)
120. Genekam (2020) Fluhunter: REAL TIME – Coronavirus (Wuhan) and bat coronaviruses. Available at: http://genekam.de/manuals/PCR-Realtime/_Ref_FR476-coronavirus2020%20and%20bat%20virusesrealtime.pdf (accessed 06 Feb 2020)
121. Genekam (2020) Fluhunter: Realtime Coronavirus (Wuhan strain), bat coronaviruses and MERS Available at: http://genekam.de/manuals/PCR-Realtime/_Ref_FR477-Wuhan-bat%20coronavirus%20and%20MERS.pdf (accessed 06 Feb 2020)
122. Genekam (2020) Fluhunter: REAL TIME – Coronavirus 2020 Wuhan und Influenza A Available at: http://genekam.de/manuals/PCR-Realtime/_Ref_FR479-novel%20coronavirus%202020%20and%20influenzaA-realtime.pdf (accessed 06 Feb 2020)
123. Thermo Fisher Scientific (2020) Genetic Analysis Solutions for Coronavirus 2019-nCoV. Available at: https://www.thermofisher.com/sg/en/home/clinical/clinical-genomics/pathogen-detection-solutions/genetic-analysis-coronavirus-2019-nCoV.html (accessed 06 Feb 2020)
124. Livzon (2020) Voluntary announcement progress of research and development products by a controlling subsidiary. 04 Feb 2020. Available at: https://www1.hkexnews.hk/listedco/listconews/sehk/2020/0213/2020021301032.pdf (accessed 21 Feb 2020)
125. Ho D et al (2020) Hong Kong researchers create fastest coronavirus diagnostic test to date. BioWorld. 07 Feb 2020. Available at: https://www.bioworld.com/articles/432927-hong-kong-researchers-create-fastest-coronavirus-diagnostic-test-to-date (accessed 10 Feb 2020)
126. The Hong Kong University of Science and Technology (2020) HKUST Research Team Invents World's Fastest Coronavirus Detection Device Offering Diagnostic Results in 40 Minutes. 06 Feb 2020. Available at: https://www.ust.hk/news/research-and-innovation/hkust-research-team-invents-worlds-fastest-coronavirus-detection (accessed 10 Feb 2020)
127. Tan A (2020) Coronavirus: Genomic 'red flags' to determine if patients are infected with virus originating from Wuhan. . The Straits Times. 7 Feb 2020. Available at:

https://www.straitstimes.com/singapore/health/coronavirus-genomic-red-flags-to-determine-if-patients-are-infected-with-virus (accessed 19 Feb 2020)
128. Butkus B (2020) Qiagen Readying Updated Respiratory Panel for Emergency 2019-nCoV Testing. 11 Feb 2020. Available at: https://www.genomeweb.com/pcr/qiagen-readying-updated-respiratory-panel-emergency-2019-ncov-testing#.XkT5hC17Ech (accessed 13 Feb 2020)
129. Gov.uk (2020) PHE novel coronavirus diagnostic test rolled out across UK. 07 Feb 2020. Available at: https://www.gov.uk/government/news/phe-novel-coronavirus-diagnostic-test-rolled-out-across-uk (accessed 11 Feb 2020)
130. Cepheid (2020) Cepheid Announces Development of Test for New Coronavirus Strain (2019-nCoV). 10 Feb 2020. Available at: http://cepheid.mediaroom.com/2020-02-10-Cepheid-Announces-Development-of-Test-for-New-Coronavirus-Strain-2019-nCoV (accessed 02 Mar 2020)
131. Mobidiag (2020) Development of Novodiag® assay for safe and easy molecular testing of novel coronavirus and influenza viruses 10 Feb 2020. Available at: https://mobidiag.com/2020/02/10/development-of-novodiag-assay-for-safe-and-easy-molecular-testing-of-novel-coronavirus-and-influenza-viruses/ (accessed 02 Mar 2020)
132. Newsfile (2020) Sona Develops Rapid Screening Test for Coronavirus. 10 Feb 2020. Available at: https://www.newsfilecorp.com/release/52268/Sona-Develops-Rapid-Screening-Test-for-Coronavirus (accessed 03 Mar 2020)
133. Newsfile (2020) Sona announces key partner for Coronavirus Rapid Screening Test. 13 Feb 2020. Available at: https://www.newsfilecorp.com/release/52396/Sona-announces-key-partner-for-Coronavirus-Rapid-Screening-Test (accessed 03 Mar 2020)
134. London Stock Exchange (2020) HiberGene to collaborate on Coronavirus test. 11 Feb 2020. Available at: https://www.londonstockexchange.com/exchange/news/market-news/market-news-detail/other/14417997.html (accessed 03 Mar 2020)
135. Hamilton P (2020) Coronavirus test fast-tracked by Dublin company Hibergene. The Irish Times. 12 Feb 2020. Available at: https://www.irishtimes.com/business/health-pharma/coronavirus-test-fast-tracked-by-dublin-company-hibergene-1.4170798 (accessed 02 Mar 2020)
136. Nicola S (2020) A Berlin Biotech Company Got a Head Start on Coronavirus Tests. Bloomberg. 12 Mar 2020. Available at: https://www.bloomberg.com/news/articles/2020-03-12/a-berlin-biotech-company-got-a-head-start-on-coronavirus-tests (accessed 12 Mar 2020)
137. GenomeWeb (2020) Seegene Gets Emergency Use Approval in Korea for Novel Coronavirus Test. 18 Feb 2020. Available at: https://www.genomeweb.com/pcr/seegene-gets-emergency-use-approval-korea-novel-coronavirus-test#.Xk3ffJMzYgo (accessed 20 Feb 2020)
138. PR Newswire (2020) Seegene launches KFDA Approved COVID-19 Assay. 18 Feb 2020. Available at: https://www.prnewswire.com/news-releases/seegene-launches-kfda-approved-covid-19-assay-301005858.html (accessed 21 Feb 2020)
139. Kim S-g et al (2020) Korean IVD firms fast-tracked to roll out COVID-19 test kits. 02 Mar 2020. Available at: https://pulsenews.co.kr/view.php?year=2020&no=218001 (accessed 12 Mar 2020)
140. EUROIMMUN AG (2020) Products - SARS-Coronavirus. Available at: https://www.euroimmun.com/products/indications/infektions-serologie/weitere-parameter/sars-coronavirus.html (accessed 02 Mar 2020)
141. EUROIMMUN AG (2020) Tests for detection of antibodies against SARS-CoV-2 now available. 21 Feb 2020. Available at: https://www.coronavirus-diagnostics.com (accessed 28 Feb 2020)
142. Stiba K (2020) Tests for detection of antibodies against SARS-CoV-2 now available. EUROIMMUNBlog. 21 Feb 2020. Available at: https://www.euroimmunblog.com/tests-for-detection-of-antibodies-against-sars-cov-2-now-available/ (accessed 28 Feb 2020)
143. SolGent (2020) DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit CE-IVD. Available at: http://www.solgent.com/english/sub03020102/view/id/45 (accessed 12 Mar 2020)
144. 360Dx (2020) Snibe Diagnostic Receives CE Mark for SARS-CoV-2 Kits, Immunoassay System. 28 Feb 2020. Available at: https://www.360dx.com/regulatory-news-fda-approvals/snibe-diagnostic-receives-ce-mark-sars-cov-2-kits-immunoassay-system#.XmisJagzaUk (accessed 11 Mar 2020)
145. Snibe Diagnostic (2020) The world's first 2019-nCoV CLIA Kits received CE mark. 06 Mar 2020. Available at: http://www.snibe.com/zh_en/en_newsView.aspx?id=576 (accessed 11 Mar 2020)

146. ELITech Group (2020) Coronavirus (COVID 19): New CE-IVD Kit now available worldwide. 03 Mar 2020. Available at: https://www.elitechgroup.com/news/coronavirus-covid-19-new-ce-ivd-kit-now-available-worldwide (accessed 11 Mar 2020)
147. GenomeWeb (2020) OsangHealthcare Gets CE Mark for SARS-CoV-2 Detection Kit. 04 Mar 2020. Available at: https://www.genomeweb.com/molecular-diagnostics/osanghealthcare-gets-ce-mark-sars-cov-2-detection-kit#.XmicAKgzaUl (accessed 11 Mar 2020)
148. GenomeWeb (2020) Integrated DNA Technologies Authorized Under CDC EUA to Provide SARS-CoV-2 Test Kits. 03 Mar 2020. Available at: https://www.genomeweb.com/pcr/integrated-dna-technologies-authorized-under-cdc-eua-provide-sars-cov-2-test-kits#.Xmism6gzaUk (accessed 11 Mar 2020)
149. Integrated DNA Technologies (2020) 2019 Novel Coronavirus (2019-nCoV). Available at: https://www.idtdna.com/pages/landing/coronavirus-research-reagents (accessed 11 Mar 2020)
150. Genomica (2020) Spanish Biotech Company Receive CE-IVD Marking on Two Covid-19 Diagnostic Test Kits. rapidmicrobiology. 10 Mar 2020. Available at: https://www.rapidmicrobiology.com/news/spanish-biotech-company-receive-ce-ivd-marking-on-two-covid-19-diagnostic-test-kits (accessed 11 Mar 2020)
151. US FDA (2020) New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel (Wadsworth Center, NYSDOH) - Letter of Authorization. 10 Mar 2020. Available at: https://www.fda.gov/media/135661/download (accessed 11 Mar 2020)